Application No.: 10/811,420 Docket No.: 10112/004001

## **REMARKS**

Please reconsider the application in view of the above amendments and the following remarks. Applicant thanks the Examiner for carefully considering this application.

## **Disposition of Claims**

Claims 1-9 are pending in this application. Claims 1 and 5-7 are independent claims. The remaining claims depend, directly or indirectly, from claim 1.

#### Claim Amendments

Claims 1 and 5-8 have been amended to clarify the invention recited and to correct typographic errors. No new matter is introduced by these amendments as support for these amendments may be found, for example, in Examples 1-8.

# Claim Rejections under 35 U.S.C. § 112 & § 101

Claim 8 was rejected under 35 U.S.C. § 112 & § 101. By way of this reply, claim 1 has been amended to clarify the invention recited. Claim 1 recites a method for treating acne, comedo, or zit by applying a composition, as defined in claim 1, to skin of a subject in need of such treatment.

Applicant respectfully asserts that the amended claim 1 recites a patentable subject matter and is clear and definite. Accordingly, withdrawal of this rejection is respectfully requested.

### Rejection(s) under 35 U.S.C. §103(a)

Claims 1-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over Murad (U.S. Patent No. 6,630,163), in view of Murad (U.S. Patent No. 5,962,517), and further in view of Gildenburg et al. (U.S. Patent No. 6,217,852). Claims 1 and 5-8 have been amended. To the

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extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

As discussed in the present specification, prior art compositions often include vitamin A or its derivatives (e.g., Vitamin A acid). Vitamin A derivatives, especially vitamin A acid, may make the skin sensitive to light and may lead to dry skin, red swelling, itching and dermatitis. (see paragraph [0012] in U.S. 2004/0228908).

Embodiments of the invention use carotene instead of vitamin A (or its derivatives). Although carotene is a precursor to vitamin A and can be converted via multiple enzymatic steps to vitamin A in our body, carotene and vitamin A are distinct chemicals. Therefore, a composition comprising carotene is distinctly different from that containing vitamin A, and vice versa.

Amended independent claims 1 and 5-7 each recite a topical composition including 1-3% carotene, but substantially free of vitamin A or vitamin A derivatives.

In contrast to embodiments of the invention, Murad (U.S. Patent No. 6,630,163) discloses method of treating dermatological disorders with fruit extracts. (Abstract). Specifically, the "dermatological agent includes at least one fruit extract from pomegranate in an amount sufficient to neutralize free radicals." (Col. 6, lines 27-29). There is no teaching of using carotene at 1-3%.

Murad (U.S. Patent No. 5,962,517) discloses pharmaceutical compositions for treating acne. The composition includes at least one of a vitamin C source, burdock root, yellow dock root, horsetail extract, a catechin-based composition, a vitamin B<sub>1</sub> source, a vitamin B<sub>2</sub> source, a

vitamin  $B_3$  source, a vitamin  $B_5$  source, and a vitamin E source. (Abstract). The compositions also include vitamin A. Murad teaches that "vitamin A is necessary for healthy skin cell growth and tissue formation. Its function is to inhibit the production of excess skin cells that eventually flake off and tend to clog pores." (Col. 5, lines 60-63). Therefore, all compositions taught by Murad include vitamin A as a main component. (see Claim 1).

Gildenburg et al. (U.S. Patent No. 6,217,852) teaches personal cleansing compositions having photoprotective agents. Specifically, Gildenburg et al. taught a composition for use as a sunscreen applied during washing. The composition includes photoprotective agents of the organic type (e.g., octylmethyoxy cinnamate and oxybenzone), the inorganic type (e.g., titanium oxide and zinc oxide), or combinations of the organic and inorganic agents. (Abstract) Therefore, Gildenburg et al. clearly fails to teach or suggest the compositions recited in the claims of the present invention.

In view of the above, Murad (U.S. Patent No. 6,630,163), Murad (U.S. Patent No. 5,962,517), and Gildenburg et al. (U.S. Patent No. 6,217,852), whether considered separately or in combination, fail to teach or suggest each and every limitation of the independent claims 1 and 5-7. Specifically, these references fail to teach or suggest a composition comprising 1-3% w/w carotene, but substantially free of vitamin A or vitamin A derivatives.

Because Murad (U.S. Patent No. 6,630,163), Murad (U.S. Patent No. 5,962,517), and Gildenburg et al. (U.S. Patent No. 6,217,852) fail to teach or suggest at least the above limitations of amended claims 1 and 5-7, claims 1 and 5-7 are patentable over these references. Dependent claims should also be patentable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

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**Obviousness Type Double Patenting Rejection** 

Claims 1-9 were rejected under the judicially created obviousness type double patenting

as being unpatentable over claims 1-10 & 15-17 of serial No. 11/446,051.

A terminal disclaimer pursuant to 37 C.F.R. § 1.131 is filed herewith. Accordingly,

withdrawal of this rejection is respectfully requested.

Conclusion

Applicant believes this reply is fully responsive to all outstanding issues and places this

application in condition for allowance. If this belief is incorrect, or other issues arise, the

Examiner is encouraged to contact the undersigned or his associates at the telephone number

listed below. Please apply any charges not covered, or any credits, to Deposit Account 50-0591

(Reference Number 10112/004001).

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Respectfully submitted,

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Attachments